IN " UNITED STATES PATENT AND

. 1013 Rec'd PCT/PTO 2 3 JAN 2002 DEMARK OFFICE

Applicant: Ortho Helix Limited

Kay, David B

Examiner:

#4

International Application No.: PCT/US96/13570

Group Art Unit:

International Filing Date: August 19, 1996

Date: February 19, 1998

For: OPEN HELICAL ORGANIC TISSUE ANCHOR AND METHOD OF FACILITATING HEALING

Commissioner Of Patents and Trademarks

Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

This invention relates to a tissue anchor which is an open helix of biocompatible material having a slope of from 0.5 turns per centimeter to 10 turns per centimeter, a length from 3 millimeters to 75 millimeters, a diameter of from 1.5 millimeters to 11 millimeters, and an aspect ratio of from about 3 to about 5 to 1. The anchor can have a head which is capable of securing or clamping tissue together, such as holding a suture in hole to secure a ligament or tendon to bone. The anchor can also have a head which causes an inward, compressive loading for use in fastening bone to bone, orthopedic plates to bone, or cartilage to bone.

As authorized and encouraged under 37 C.F.R. §1.97-1.99, applicant hereby cites as a means of complying with the duty of disclosure set forth in 37 C.F.R. §1.56, the following patents and/or documents, copies enclosed, which the Examiner should consider with respect to the above-identified United States Patent Application:

| PATENT/DOCUMENT | DATE | NAME/COUNTRY |
|---------------------------------------|-------------------|--------------------------------|
| NO. | · | |
| 3,499,222 | Must 10, 1070 | |
| 4,590,928 | March 10, 1970 | Linkow et al./U.S. |
| | May 27, 1986 | Hunt et al./U.S. |
| 4,870,957 | October 3, 1989 | Goble et al./U.S. |
| 5,203,787 | April 20, 1993 | Noblitt et al./U.S. |
| 5,268,001 | December 7, 1993 | |
| 5,417,691 | May 23, 1995 | Nicholson et al./U.S. |
| 5,370,662 | | Hayhurst et al./U.S. |
| 5,053,047 | December 1994 | Stone et al./U.S. |
| · · · · · · · · · · · · · · · · · · · | October 1991 | Yoon/U.S. |
| 2,570,465 | October 1951 | Lundholm/U.S. |
| 2,414,882 | January 1947 | |
| 5,582,616 | December 10, 1996 | Longfellow/U.S. Boldue et al. |

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| IN - International Search Report | FOREIGN ART March 6, 1997 | ISA/US |
|--|--|----------------------------|
| PCT/US96/13570 652940 WO94/28811 | December 1994 | USSR W.I.P.O. E.P.O. |
| 374,088 1,071,297 0 663 184 A1 | June 1990 February 1984 January 13, 1995 | Soviet Union E.P.O. |

USSR Document No. 652940 relates to a fastening member having a slotted head and a two pitch special helix member.

A copy of each publication is included for the express purpose of providing the Patent and Trademark Office with an ample opportunity to evaluate the same and to arrive at an independent assessment of their materiality, if any, with regard to the examination of the application.

In reviewing the enclosed copies of the above publications, the Examiner is requested to ignore any underscoring or highlighting which may appear because such markings may or may not have any relationship to the subject matter of the above-identified application.

The copies being submitted with this Information Disclosure Statement are the best copies available at this time.

An examination of the present application considering the above documents is requested.

Respectfully submitted,

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LFS/sms Enclosures

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